DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 19

The Honorable Jon S. Corzine
United States Senate
Washington, D.C. 20510-3004

Dear Senator Corzine:

Thank you for the letter of August 22, 2002, on behalf of Mrs. Danene Gooding of Ringoes, New Jersey. Mrs. Gooding sent several signed citizen petitions requesting that the Food and Drug Administration (FDA or the Agency) amend its food labeling regulations to require the provision of source information for modified food starch, spices, natural and artificial flavorings, and other non-specific ingredients.

Mrs. Gooding's daughter has celiac disease which causes an intolerance to the protein component of the gluten in wheat, barley, rye, and oats. This means she needs to avoid food products containing these grains. Mrs. Gooding is concerned that food manufacturers are including these grains in their products without stating so on the label's ingredient statement.

FDA appreciates the difficulties faced by persons with food allergies and food intolerances. Being able to identify and avoid specific ingredients is of great importance to such persons. We have enclosed a Notice to Manufacturers that FDA distributed to food manufacturers, trade associations, and other food industry groups. It advises the industry on the steps to take to ensure that allergens are declared on food labels. In the Notice, we ask manufacturers to examine their product formulations for known allergens and to be sure to declare the presence of these ingredients in the ingredient statement on the label. Please note that wheat is included in the list of common allergens. We believe that the inclusion of wheat in the list will help enable persons who have celiac disease to avoid many products containing gluten.

By way of background, the Federal Food, Drug, and Cosmetic (FD&C) Act requires, in virtually all cases, that labels of food fabricated from two or more ingredients bear a declaration of each ingredient, by its common or usual name, in descending order of predominance, and by weight in the ingredient statement. There are two very narrow exemptions from this ingredient-labeling requirement. The first is provided in section 403(i) of the FD&C Act. It states that spices, flavorings, and certain colorings may be declared collectively without naming each one.

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The second is provided in Title 21, Code of Federal Regulations §101.100(a). It states that incidental additives, such as processing aids that are present at insignificant levels and that do not have a technical or functional effect in the finished food, do not have to be declared on the label. Since evidence suggests that some allergenic substances can cause serious allergic responses in some individuals upon ingestion of very small amounts, FDA's Notice advised manufacturers that an allergen cannot be determined to be present at an insignificant level and therefore does not qualify for an exemption.

FDA has been working with industry and consumer groups to raise awareness about the presence of allergens in foods and to identify practical approaches for the labeling of allergens. Addressing food allergen issues is a priority for FDA's Center for Food Safety and Applied Nutrition. Continuing consumer and industry education efforts and developing a strategy to improve the labeling of the most common allergens are some of the many allergen-related goals included in the current list of Agency priorities.

FDA held a public meeting on August 13, 2001, to obtain input from the public on allergen labeling issues to determine what additional actions may be necessary to assist consumers in identifying products containing allergens and to assist manufacturers in producing food products that are safe for allergenic consumers. Specifically, the meeting focused on: (1) source labeling or plain English labeling; (2) advisory labeling such as "may contain nuts;" and (3) labeling of flavorings, spices, and colors and of incidental additives. FDA has received comments for consideration regarding this issue. Your request and your constituent's letter and enclosed petitions have been included in the record (Docket #00P-1322). Please be assured that we will consider all comments before making a final decision on this issue.

Enclosed is a recent article entitled, "Food Allergen Awareness: An FDA Priority," that may be of interest to you and your constituent. This article and other allergen-related Agency information are available at the Agency's "Information about Food Allergies" website: www.cfsan.fda.gov/~dms/wh-alrgy.html.

Thank you again for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,

Kristina Harper

for Amit K. Sachdev
Associate Commissioner
for Legislation

Enclosures

cc: Food and Drug Administration, HFA-305
(Docket #00P-1322)

JON S. CORZINE
NEW JERSEY

COMMITTEES
BANKING, HOUSING, AND URBAN AFFAIRS
ENVIRONMENT AND PUBLIC WORKS
JOINT ECONOMIC

United States Senate

WASHINGTON, DC 20510–3004

502 SENATE HART OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224–4744

ONE GATEWAY CENTER
11TH FLOOR
NEWARK, NJ 07102
(973) 645–3030

208 WHITE HORSE PIKE
SUITE 18–19
BARRINGTON, NJ 08007
(856) 757–5353

August 22,2002

MEMO

To: Dockets Management Branch HFA-305
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

From; June S. Fischer
Special Assistant
Jon S. Corzine
United States Senator

Attached hereto are citizens' petitions that were sent to this office. They do address a very real and serious concern. I am forwarding these on to you in the hope that your agency will give this matter your prompt attention and respond accordingly.

JSF

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